DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John W. Kowalski, Jr.
President
J & J Millcreek Farm, Inc.
13 Millcreek Lane
Stuyvesant, New York 12173

July 29, 2002

File No.: NYK 2002-39

Dear Mr. Kowalski:

On June 25, 2002, U.S. Food and Drug Administration investigators conducted an inspection at your farm located in Stuyvesant, New York. This inspection confirmed that in February and March 2002 you offered two animals for sale for food that were adulterated within the meaning of Sections 402 (a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed serious deviations from the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530). These deviations caused an animal drug to become adulterated within the meaning of Section 501(a)(5).

On or about February 11, 2002, you offered for sale a cow identified with farm tag 2045 for slaughter as human food. The cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 15.98 parts per million (ppm) neomycin in kidney tissue.

On or about March 18, 2002, you offered for sale a cow identified with farm tag 1671 for slaughter as human food. The cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 8.60 ppm neomycin in kidney tissue.

A tolerance of 7.2 ppm has been established for residues of neomycin in edible tissues of cattle (Title 21 Code of Federal Regulations 556.430). The presence of this drug in excess of the tolerance in the kidney tissues of these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

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Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of drugs from edible tissues. Foods from animals held under such conditions are adulterated under Section 402(a)(4).

You also caused the drug Neomycin Oral Solution, containing neomycin, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the labeling. Your injection of this oral drug into the mammaries of the two cows causes the drug to be unsafe for use.

You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Richard T. Trainor, Compliance Officer, at the following address: FDA, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely,

for Jerome G. Woyshner
District Director